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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,732	12/20/2001	Thomas J. Bormann	440525/PALL	9021

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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,732	BORMANN ET AL.	
	Examiner	Art Unit	
	Krishnan S Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-22 and 24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 15-22 and 24-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13, 15-22 and 24-34 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 15-22 and 31-34, rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 267 286 A1 in view of EP 0630 675 A1 and Onishi et al (US 5,547,576)

EP-286 teaches a filter comprising one or more fibrous filter elements (examples) having surface nitrogen and oxygen ratio as in claim 1 (pages 6,9,10 and 23: the N-atom content of the surface given in page 10 meets the ratio with the hydrophilic surface modifiers like amido groups in page 9 or 23), elements surface-hydroxylated/carboxylated relative to the bulk as in claims 1-9 and 31-34 (see page 9 – hydroxyl groups; page 23-HEMA).

EP-286 does not teach 'at least two filter elements wherein the surface of one filter element is substantially non-hydroxylated'. Onishi-576 teaches a filter with substantially non-hydroxylated surface having nitrogen and oxygen as in the instant

claims (example 6: compounds used do not have hydroxyl groups, and hydroxyl groups are not formed in the reactions). EP-675 teaches filter elements for leukocyte separation (platelet non-adsorbing – page 3, and lines 20-27 of page 4) and leukocyte/platelet separation (pages 4 and 5 – with platelet-adsorbing layer), layers specific for leukocyte separation and platelet removal (lines 39-51, page 7) having surface N/O groups and hydroxyl groups. It would be obvious to one of ordinary skill in the art at the time of invention to use the teachings of Onishi and EP-675 in the teaching of EP-286 to have a filter having multiple layers for leukocyte and platelet separation as taught by EP-675, with a layer substantially non-hydroxylated as taught by Onishi for selectively removing viruses, etc (Onishi example 6 and col 1 lines 9-11).

Multiple layers are taught as in claims 4-6 (EP-675: page 4 lines 12-16 and 49-56, col 7 lines 27-56); additional layers in claim 4 are only duplication ((Note: mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*; In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), and a mere reversal of parts (In re Gazda 219 F.2d 449. 104 USPQ 400 (CCPA 1955) or rearrangement of parts (In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) are unpatentable. In the present case, between claims 5 and 6, applicants have the order of layers arranged in all possible ways, indicating that the order of arranging the layers make no difference (species claims – obvious equivalents).

The limitation, '...hydroxylated .... is aminated ...', as in claim 7 and 8 (page 23). The hydroxylated surfaces include carboxyl groups as in claim 10 (page 23). EP-286 in

view of EP 675 and Onishi teach separate elements, one set having N/O ratio and another set having excess surface hydroxyl groups as in the instant claims, and separate elements having excess surface carboxyl and excess surface hydroxyl groups as in claim 32 and 33 (EP-675 col 5 lines 1-18, EP-286 page 23). EP 675 teaches filter for filtering and separating leukocytes and platelets having elements (layers) with excess surface N/O and carboxy groups (page 5 lines 9-18), and other elements having excess surface hydroxy groups (page 7 lines 27-56).

Re claims 11-13 and 15, zeta potential as in claim 11, and CWST as in claims 12, 13 and 15 are all material properties, and would be similar for similar materials. [[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977))].

Claims 16-22 add further limitations as follows: EP-286 in view of EP-675 and Onishi teach a housing with inlet and outlet as in claim 16 (fig 2 of EP-286), plasma passes through and leukocytes and platelets do not as in claim 17 (see EP-675 tables); re C3a as in claims 18,19 and 22, similar filter structure would give similar results for C3a as obtained by the applicant. Re leukocyte and platelet counts in the plasma

product, this factor would depend on the counts in the original plasma in addition to the efficiency of the filter (see tables in EP-286, table 1 of Onishi and table 2 of EP 675).

Response to Arguments

Applicant's arguments filed 5/17/04 have been fully considered but they are not persuasive.

In response to applicants' argument that the Onishi teaching of N/O ratio is not understood, Onishi teaches eq/g of amino groups in example 6. This, with the amount of uptake of glycidyl acrylate gas, etc, during the graft polymerization on the surface would provide one of ordinary skill in the art with a measure for the ratio of N/O on the polypropylene membrane surface.

Arguments re the EP-675 ref that there is no teaching in EP 675 that an element should have both nitrogen and oxygen: the reference does not explicitly teach that there must be N and O present, but it does teach that the substrate is subjected to plasma treatment, graft copolymerization with glycidyl methacrylate (contains O), and then cationic agent (amino compound – contains N) is bonded (page 5 lines 9-18), which would give both N and O on the surface.

In response to applicants' argument that claim 5 recite alternating arrangement, claim 6 recites the other possible alternating arrangement; and therefore, claims 5 and 6 are equivalent, as shown in the rejection. Since the applicant has not shown with evidence that in the species claims 2-6, the alternating arrangements and the multiple layers are un-obvious non-equivalents, claims are not patentable.

In response to the argument that the office action has not explained what similar materials are in the inherency rejection, the references teach membranes having materials similar to what are being claimed; therefore the properties claimed would also be inherently present in the membranes taught by the references, unless the applicants can show otherwise. Re claim 11, it depends from claim 1, and there are no limitations in these claims that would make them distinct from the teachings of the references to have the properties any different. Argument re EP-675 is moot since the rejection has changed.

Conclusion

This is an RCE of applicant's earlier Application No. 09/936,732. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan Menon
Patent Examiner

W. L. WALKER
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